REMARKS

Claims 61-67 are pending. Claim 68 is new. This is responsive to the Notice of Non-Compliant Amendment. The Notice of Non-Compliant Amendment indicates that claim 63 has been presented twice. Applicants have amended the claim listing so that claim 63 is presented once. The canceled claim is now presented as new claim 68. Support for this amendment may be found throughout the specification, see e.g., page 21, lines 14-23. No new matter is added by the amendment.

Cancellation of claims should in no way be construed as an acquiescence to any of the Examiner's rejections. Cancellation of claims are being made solely to expedite prosecution of the present application and do not, and are not intended to, narrow the claims in anyway. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

Applicants have resubmitted the entire response for the courtesy of the Examiner.

Priority

The Office Action states that "[a]pplicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C 119(e)." Applicants respectfully disagree.

Both disclosures in the provisional application 60/024,845 (the "'845 provisional") and the instant application that claims priority to this provisional provide full support for pending claims. This support is shown graphically in Appendix A, showing a nucleotide sequence alignment and Appendix B, showing a protein alignment, both attached herewith for the Examiner's convenience. These appendices label sequences disclosed in the '845 provisional as '845Prov. The sequence disclosed in the instant application is labeled '043. The appendices also align SEQ ID 772 of Kunsch, discussed infra.

The sequence alignments show, contrary to the Examiner's assertion, that claim 61, reciting in part a nucleotide sequence that hybridizes under stringent conditions to a complementary strand of a polynucleotide having SEQ ID 1, is fully supported by the disclosure in the '845 provisional. The '845 provisional discloses a nucleotide sequence that differs from SEQ ID NO: 1 by only three nucleotides. Further, as the Examiner notes, for a nucleotide

sequence to hybridize to SEQ ID NO: 1, as recited in claim 61, the nucleotide sequence need not be complementary over the entire length. Office Action p. 7 ll. 7-9.

The protein sequence alignment between the '845 provisional and the instant disclosure differs by only one residue at the C-terminal, as the Examiner notes. The nucleotide and protein sequence disclosed in the '845 provisional therefore fully supports claim 61 which also recites, in part, a nucleotide encoding a polypeptide comprising an amino acid sequence having at least 95% identity to the amino acid sequence set forth in SEQ ID NO:2.

Rejection of claims under 35. U.S.C. 112

Claims 61-67 stand rejected under 35 U.S.C. 112, first paragraph. The Examiner asserts that because the specification, while being enabled for an isolated nucleic acid sequence comprising a nucleotide sequence that encodes a polypeptide that reduces crotonyl-CoA or crotonyl-ACP and comprises an amino acid sequence either identical to SEQ ID NO: 2, or differing from SEQ ID NO:2 by substitution, insertion or deletion of a single amino acid, does not reasonably provide enablement for a nucleotide sequence encoding a polypeptide that reduces crotonyl-CoA or crotonyl-ACP and differs from SEQ ID NO:2 by insertion, deletion or substitution [of] more than one amino acid. The Examiner indicates that this rejection relates to parts (d) and (e) of claim 61, part (g) of claim 61 as it relates to parts (d) and (e), and claims 62-67 as these claims relate to parts (d) and (e). Applicants respectfully traverse this rejection.

It is a well-settled tenet of patent law that "mere breadth" is not a proper test under 112 first paragraph. See, In re Marzocchi et al., 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Furthermore, the Federal Circuit has also held that a "patent specification [is] enabling even though it listed elements that could form thousands of end products, some of which may not be operative." Atlas Powder Co. V. E.I. du Pont de Nemours & Co., 224 U.S.P.Q. 409 (Fed. Cir. 1984). Accordingly, even if the claims were to read on some inoperative embodiments the law states that the specification would still meet the requirements of section 112.

Applicants note that a long pedigree of cases have held that there is no requirement of *a priori* knowledge of all specific embodiments of the claimed invention. Enablement is not precluded even if some experimentation is necessary. Applicants contend that the specification provides sufficient guidance with respect to polypeptides that reduce crotonyl-CoA or crotonyl-

ACP, such that a person of ordinary skill in the art could make and use the claimed nucleotide sequences without undue experimentation, relying on the specification and knowledge in the art. The teachings of the specification clearly enable the skilled artisan to make and use a vast range of hybrid polypeptides at least for the following reasons.

The Examiner asserts that "the specification contains no guidance or citations of relevant prior art that would inform the skilled artisan of which amino acid residues of SEQ ID NO: 2 could be altered without adversely affecting its folding or biological activity." Applicants respectfully submit that, a person of skilled in the art, can readily determine whether a polypeptide as recited in claim 61 is capable of reducing crotonyl-CoA or crotonyl-ACP using for example, the enzyme activity analysis disclosed in the instant specification at for example, page 52 ll. 20-28, Example 2, and page 42 ll. 17-25 describing screening for detection of the reduction of crotonyl-CoA by measuring the consumption of NADH.

Additionally, Applicants respectfully remind the Examiner that "[a] specification is presumed to be enabling and the U.S. Patent and Trademark Office (PTO) has the burden of establishing a prima facie case of lack of enablement." In re Angstadt, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). To make a prima facie case of lack of enablement, the PTO must come forward with reasons, supported by the record as a whole, showing why the specification fails to enable one of ordinary skill in the art to make and use the claimed invention. Id. The burden is on the PTO to establish that experimentation would be undue, taking into consideration the eight factors that are to be considered in determining whether a disclosure requires undue experiment. In re Wands, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). In applying these eight factors to the instant case it is evident from the above discussion that the level of skill in this art was very high at the time the application was filed, and the experimental techniques needed to practice the invention were well known and exemplified in the specification as filed. Accordingly, Applicants respectfully submit that armed with the teachings of the specification and the contemporary knowledge in the art, the skilled artisan would be able to practice the claimed invention without further undue experimentation.

Screening techniques taught in the specification combined with those techniques available in the art at the time the present invention was made provide sufficient guidance for generating nucleotide sequences that both encode the recited polypeptides and are capable of

reducing crotonyl-CoA or crotonyl-ACP, as recited in claim 61. Accordingly, Applicants assert that the specification, in light of the art at the time the present invention was made, is enabling for a sufficient number of other permutations of the claimed nucleotide sequences to entitle Applicants to the invention as presently claimed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of claims under 35 U.S.C. § 102(e)

Claims 61-67 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kunsch et al. (U.S. Patent No. 6,593,114), which claims priority through U.S.S.N. 08/781,986 filed 1/3/1997. The Office Action states that Kunsch et al. discloses a polynucleotide comprising SEQ ID NO: 772 and that "[n]ucleotides 24-704 of SEQ ID NO: 772 correspond[] to nucleotides 1-678 of instant SEQ ID NO: 1." The rejection is respectfully traversed.

Applicants assert that U.S. Patent No. 6,593,114 is not a proper reference under 35 U.S.C. § 102(e) because the earliest priority date for that patent which supports the subject matter used to make this rejection will fall after Applicants' earliest filing date (August 28, 1996). As Applicants note above, the priority document fully supports claims 61-67. In particular, the priority document discloses a sequence with more than 95% identity over the corresponding claimed sequence region. Therefore, the earliest filing date of the instant application is August 28, 1996, and as such U.S. Patent No. 6,593,114 does not qualify as prior art under 35 U.S.C. § 102(e). Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 61-67 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,432,670. Applicants respectfully request that the Examiner hold in abeyance this rejection until allowable subject matter is indicated.

Conclusion

In view of the above remarks and the amendments to the claims, it is believed that this application is in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

Respectfully submitted,

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